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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,376	04/08/2002	Christopher Ralph Franks	5585-61760	7113

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/4

Office Action Summary	Application No.	Applicant(s)	
	10/009,376	FRANKS ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-39,41,42,44,45,47 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-39,41,42,44,45,47 and 48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-665, claim(s) 1-39, 44, 47, and 48 partially, drawn to a composition comprising a proliferatively active moiety linked to nucleic acid material which is associated with a protective material, wherein the proliferatively active moiety is selected from the group consisting of: IL-2,desala$_1$-IL2 ser 125, IL-6, TNF, M-CSF, IFN-alpha, IFN-beta, IFN-gamma, FGF, IGF-I, TGF-beta, GM-CSF, SCF, G-CSF, Epo, Multi-CSF, E-CSF, PDGF and TGF-beta2, and wherein the nucleic acid material is selected from the group consisting of a thymidine kinase gene, a cytosine deaminase gene, a cytochrome P-450 gene, a bacterial nitroreductase gene, a defect correcting gene, an immunogene, and an antisense nucleotide sequence, and wherein the protective material is selected from the group consisting of lipids, polylysine, polylysine derivatives, dendrimers and polyethyleneimine. The number of groups was arrived at by multiplying the number of proliferatively active moieties (19) by the number of nucleic acids (7) and the number of protective materials (5) recited in the claims. Applicant must elect for examination a single composition comprising a proliferative moiety, a nucleic acid material, and a protective material.

Groups 666-1330, claims 41 and 42 drawn to methods of treating or inhibiting the development of an autoimmune disease by administering a composition comprising a proliferatively active moiety linked to nucleic acid material which is associated with a protective material, wherein the proliferatively active moiety is selected from the group consisting of: IL-2,desala$_1$-IL2 ser 125, IL-6, TNF, M-CSF, IFN-alpha, IFN-beta, IFN-gamma, FGF, IGF-I, TGF-beta, GM-CSF, SCF, G-CSF, Epo, Multi-CSF, E-CSF, PDGF and TGF-beta2, and wherein the nucleic acid material is selected from the group consisting of a thymidine kinase gene, a cytosine deaminase gene, a cytochrome P-450 gene, a bacterial nitroreductase gene, a defect correcting gene, an immunogene, and an antisense nucleotide sequence, and wherein the protective material is selected from the group consisting of lipids, polylysine, polylysine derivatives, dendrimers and polyethyleneimine.

Groups 1331-1995, claims 41 and 42 drawn to methods of treating or inhibiting the development of a retroviral disease by administering a composition comprising a proliferatively active moiety linked to nucleic acid material which is associated with a protective material, wherein the proliferatively active moiety is selected from the group consisting of: IL-2,desala$_1$-IL2 ser 125, IL-6, TNF, M-CSF, IFN-alpha, IFN-beta, IFN-gamma, FGF, IGF-I, TGF-beta, GM-CSF, SCF, G-CSF, Epo, Multi-CSF, E-CSF, PDGF and TGF-beta2, and wherein the nucleic acid material is selected from the group consisting of a thymidine kinase gene, a cytosine deaminase gene, a cytochrome P-450 gene, a bacterial nitroreductase gene, a defect correcting gene, an immunogene, and an antisense nucleotide sequence, and wherein the protective material is selected from the group consisting of lipids, polylysine, polylysine derivatives, dendrimers and polyethyleneimine.

Groups 1996-2660, claims 41 and 42 drawn to methods of treating or inhibiting the development of a lymphoproliferative disease by administering a composition comprising a proliferatively active moiety linked to nucleic acid material which is associated with a protective material, wherein the proliferatively active moiety is selected from the group consisting of: IL-2,desala$_1$-IL2 ser 125, IL-6, TNF, M-CSF, IFN-alpha, IFN-beta, IFN-gamma, FGF, IGF-I, TGF-beta, GM-CSF, SCF, G-CSF, Epo, Multi-CSF, E-CSF, PDGF and TGF-beta2, and wherein the nucleic acid material is selected from the group consisting of a thymidine kinase gene, a cytosine deaminase gene, a cytochrome P-450 gene, a bacterial nitroreductase gene, a defect correcting gene, an immunogene, and an antisense nucleotide sequence, and wherein the protective material is selected from the group consisting of lipids, polylysine, polylysine derivatives, dendrimers and polyethyleneimine.

Groups 2661-3325, claim 45, drawn to methods stimulating the proliferation of a lymphocyte by administering a composition comprising a proliferatively active moiety linked to nucleic acid material which is associated with a protective material, wherein the proliferatively active moiety is selected from the group consisting of: IL-2,desala$_1$-IL2 ser 125, IL-6, TNF, M-CSF, IFN-alpha, IFN-beta, IFN-gamma, FGF, IGF-I, TGF-beta, GM-CSF, SCF, G-CSF, Epo, Multi-CSF, E-CSF, PDGF and TGF-beta2, and wherein the nucleic acid material is selected from the group consisting of a thymidine kinase gene, a cytosine deaminase gene, a cytochrome P-450 gene, a bacterial nitroreductase gene, a defect correcting gene, an immunogene, and an antisense nucleotide sequence, and wherein the protective material is selected from the group consisting of lipids, polylysine, polylysine derivatives, dendrimers and polyethyleneimine.

The inventions listed as Groups 1-3325 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1, broadly drawn to a composition comprising a proliferatively active moiety linked to nucleic acid material which is associated with a protective material is anticipated by the prior art. As

such the various inventions are not linked by a special technical feature. For example WO 96 36362 disclosed a complex comprising a nucleic acid complexed to a condensing agent such as polylysine, polyarginine, protamines, or histones, modified with a ligand such as FGF. See pages 54-56. The nucleic acid could encode thymidine kinase, cytosine deaminase, or antisense (page 34, lines 22-27, or page 37, lines 14-24). Also note that Cristiano et al (Cancer Gene Therapy 3(1): 4-10, 1996) taught that polylysine could be modified with EGF and complexed to nucleic acids encoding therapeutic genes. See abstract, and page 9, column 2, lines 1-4. As such there is no special technical feature unifying the various proliferatively active moieties, the various nucleic acids, or the various protective materials recited in the claims. As a result the number of inventions is equal to the product of the numbers of proliferatively active moieties, nucleic acids, and protective materials recited in the claims. Regarding method claims 41, 42, and 45, Both Cristiano and WO 96 36362 envision methods of treating disease, so there is no special technical feature linking these claims either.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.